REMARKS

The present amendment is in response to the Office Action dated 22 February 2010, where the Examiner has rejected claims 34-51. Applicants thank the Examiner for the thorough review of the application as demonstrated by the Office Action. In the present amendment, claims 34, 37, 38, 46 and 47 have been amended. Support for the amendments can be found throughout the specification. Reconsideration and allowance of pending claims 34-51 in view of the amendments and the following remarks are respectfully requested.

A. Claim Amendments

Claims 34, 37, 38, 46 and 47 are objected to for certain informalities and have been amended as proposed by the Examiner.

Claim 34 is amended to clarify that the material for the first phase is in a fluid state capable of solidification, for consistency with the later feature that "the composition is suitable for introduction into a tissue prior to solidification of the material of the first phase to form the porous matrix".

Claim 34 is also amended to require that the first material is selected from a plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid. This is based on, for example, paragraphs 0014, 0016, 0053, 0055 and 0067 of the US application as published.

Claim 34 is also amended to require that the porous matrix has a porosity that is achieved by gaps between particles, or by incomplete liquefaction of the first phase, in addition to the inherent porosity of the particles. This is based on, for example, paragraph 0047 of the US application as published.

Claim 34 is also amended to require that the material for the first phase comprises one or more polymer and the material for the second phase comprises one or more polymer. This is based on, for example, paragraph 0021 of the US application as published.

Claim 37 is amended to refer to the solid particle material, for consistency with claim 36.

Claim 38 is amended for consistency with the fact that claim 34 now requires that the material for the first phase comprises one or more polymer and the material for the second phase comprises one or more polymer. The term "pectins" has been added to the list of specific options for claim 38, rather than included in parentheses.

The dependency of claim 46 has been corrected so that this claim refers back to claim 45.

In claim 47 the term "specialised cells such as" has been deleted and "or" has been replaced by a comma.

Applicant has amended the claims in accordance with the suggestions of the Examiner and believes that the claim objections are now overcome. Withdrawal of the objection to claims 34, 37, 38, 46 and 47 is respectfully requested.

B. 35 USC §112, first paragraph (written description)

The Office Action rejects Claims 34-51 for lack of written description pursuant to 35 U.S.C. §112, first paragraph. In particular, the Office Action asserts that there is inadequate written description of solidifying a solid in the form of a powder, grain or granule as a first phase and that working conditions have not been provided of how to solidify a solid in the form of a powder, grain or granule.

In the 112 ¶1 rejection, the Examiner has maintained his concern that the claims cover embodiments that could not have readily been carried out at the time of filing the application based on what is described in the application. The Examiner indicates that he cannot see any disclosure of how to solidify a solid in the form of a powder, grain or granule. He suggests that when particles are used in the examples, they are melted or dissolved, and therefore they are in liquid form before they are solidified.

The Examiner's concern is therefore, apparently, that there is no disclosure as to how a product would work, if it was provided in the form of particles when it was introduced into the body.

However, it is submitted that the skilled artisan would, in fact, have been able to put the invention into practice using plastic solids or flowable solid particles (in powder, grain or granule form) for the material for the first phase.

It is possible to introduce the first material into the body of the subject as solid particles within a liquid suspension. It is equally feasible to add the first material into the body of the subject as solid particles in dry form. The particles do not need to be fully melted or liquefied before delivery but rather there can be a partial melt or liquefication at the surface of the particles only. Therefore the particles do still remain as discrete particles at all times. In other words, the particles can be provided as partially liquefied, partially melted or tacky semi-solids. The particles can then fuse together in the body due to the change in surface properties of the particles that is caused with the change in temperature on introduction to the body of the subject, and solidify.

The application as filed provides various discussions of the characteristics of the material for the first phase. This includes at paragraphs 0014, 0016, 0017, 0020, 0046 and in the Examples.

From these sections it would be immediately apparent to the skilled artisan that the invention could be carried out with the first phase material being solids that are sufficiently fluid to mix with and coat or carry the second phase material, solids that are fluid but tacky, particulate or powdered material, e.g. particulate or powdered material that is soft and tacky, or polymeric material that is tacky or fully liquefied.

These sections make clear and specific reference to the use of plastic solids, partially liquefied solids, partially melted solids and tacky semi-solids. Therefore it would be clear to the skilled artisan after review of the specification that it was possible and fully envisaged that the invention could be put into practice in this manner.

Indeed, paragraph 0053 in the Examples makes clear and specific reference to the fact that the first phase is particulate and is heated but does not fully liquefy, instead becoming a tacky semi solid.

Therefore the application as filed provided the information required for the skilled artisan to comprehend and put into effect the claimed invention, where the material for the first phase is a flowable solid.

For at the least the reasons stated above, Claims 34-51 have adequate written description. Withdrawal of the rejection is respectfully requested.

C. Declaration Under 37 CFR 1.132

In support of the explanation in section B regarding the sufficiency of the written description with respect to the amended claims, Applicant submits the declaration of inventor Quirk that sets forth specific facts regarding the sufficiency of the explanation contained in the application as filed and its teaching to one skilled in the art. In accordance with the factual evidence presented in the declaration, Applicant requests that the written description rejection be withdrawn.

D. 35 USC §103(a)

Claims 34-51 stand rejected under section 103(a) as being unpatentable over U.S. Patent No. 6,841,617 ("Jeong") in view of U.S. Patent No. 6,290,729 ("Slepian"), and if necessary in further view of U.S. Patent No. 6,818,018 ("Sawhney") or U.S. Patent No. 6,129,761 ("Hubbell"). As set forth in MPEP § 2143, in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 82 USPQ2d 1385, 1395-97 (2007) the Supreme Court identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The KSR Court noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

In the office action, the Examiner has maintained that it would be obvious to modify a thermogelling polymer solution that contains cells, as described in Jeong, in order to arrive at the claimed invention, in view of Slepian. The office action also refers to Sawhney and Hubbell to provide further details regarding suitable conditions that could be used for the thermoreversible polymer of Slepian.

Jeong relates to a thermogelling biodegradable aqueous polymer solution which can be used in situ to form biodegradable implants. The thermogelling solution is designed to gel quickly at physiological conditions. There is nothing in Jeong regarding a composition that is solidifiable to form a porous matrix, where the composition comprises a first polymeric phase which is a plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid. There is also nothing in Jeong regarding compositions where there is a second polymeric phase contained within and distributed through the first phase.

Jeong therefore lacks these features of the claimed invention. Further, there is nothing in Jeong that makes the inclusion of these missing features obvious. The only teaching in Jeong is regarding a thermogelling solution. There is simply no indication or suggestion that alternative materials could or should be used as the solidifiable material to form the implant.

There is certainly no reason for the skilled artisan to be motivated to consider the use of composition that is solidifiable to form a porous matrix, where the composition comprises a first polymeric phase which is a plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid.

In fact, the use of the materials set forth in the present claims gives rise to a technical benefit over Jeong. Jeong describes the use of soft hydrogels as the material to form the implants. The nature of these materials means that they are not able to achieve macroporosity in the resultant solidified product. In contrast, the invention of the present application achieves a porous structure by gaps between particles, or by the incomplete liquefaction of the first phase. This is in addition to any inherent porosity of the particles themselves. In other words, there is always macroporosity in the solidified matrix obtained by the claims of the present application.

The achievement of macroporosity is relevant to the present invention; this feature means that diffusion can occur through the formed matrix, which can be used as a tissue scaffold. This porosity is needed for nutrient transfer and to provide space for cells to proliferate or form tissue structures. It can, for example, be highly beneficial to

encourage local endogenous cells to grow within the porous matrix when used as a tissue scaffold.

It is further noted that an advantage of the invention is that it has an open pore structure, i.e. interconnected pores connecting the centre to the surface. This is inherently achieved when pores are formed between co-attached particles.

Therefore not only does Jeong not teach or suggest the use of the particular claimed types of material for the first phase, but additionally the use of this material gives rise to particular benefits and technical advantages.

Further, there is also no teaching in Jeong to include a second material, which comprises polymer, in the thermogelling polymer solution. There is simply no motivation for a second polymeric material to be dispersed within this solution. The skilled artisan would be aware of the significance of the fact that the product was intended as a biodegradable implant that could be used as a bioactive agent delivery system, which would therefore be intended for use in the human body. Accordingly, there would be a reluctance to add additional materials unless there was a clear and specific motivation to do so, as there would inevitably be concern as to how the inclusion of further material might affect the way the product worked and its suitability for the intended use.

Slepian does not provide the missing features that would be needed to arrive at the claimed invention from Jeong. Slepian uses a biodegradable gelling liquid material, which is applied to the surface of tissue lumens to provide a barrier having either a controlled permeability to materials in the lumen and/or controlled release of incorporated bioactive agents. The material, in a fluid form, is positioned in contact with a tissue or cellular surface to be coated and is then stimulated to render it non-fluid.

Accordingly, Slepian does not teach or suggest that the composition should comprise a polymeric phase which is a plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid. Instead, Slepian clearly teaches that the solidifiable material is a gelling liquid material.

Therefore Slepian reinforces the teaching of Jeong that a liquid material should be used as the phase that is solidifiable. It in no way provides any motivation to use the plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid, that is required by the claimed invention.

As mentioned above, the use of this material gives rise to particular benefits and technical advantages, in terms of macroporosity and an open pore structure.

Slepian mentions permeability, but this is a much smaller scale than macroporosity, where there are actual pores in a matrix structure. Indeed, Slepian uses hydrogels or organogels as the gelling material and the nature of these materials means that they are not able to obtain macroporosity.

Further, Slepian also provides no teaching that a second polymeric material should be contained within and distributed through the solidifiable polymeric material.

Slepian does disclose that the polymeric material used as the biodegradable gelling material can be selected to achieve desired properties, such as the conditions under which it polymerises and its permeability. Slepian does also disclose that multiple layers of polymeric material can be used, each containing different pharmacological agents. Slepian further teaches that the physical guidance of cells can be achieved by including particles, ribbons or fibres which direct cell growth within the polymeric material.

However, Slepian does not provide the skilled artisan with any sort of teaching that he should include a second polymeric material, this second polymeric material being dispersed within the solidifiable first polymeric material. Accordingly, the combination of Jeong and Slepian fails to disclose all of the features required by the amended claims.

Sawhney and Hubbell fail to remedy the defects of Jeong and Slepian. Sawhney nad Hubbell do not provide any teaching that completes the missing features and thereby makes the subject matter of the present application obvious. Accordingly, any combination of Jeong, Slepian, Sawhney and Hubbell fails to disclose each and every element of the amended claims. Applicant therefore believes that the pending claims

are are all presently in condition for allowance and a notice of allowance is respectfully requested.

CONCLUSION

For all the foregoing reasons, early allowance of pending claims 34-51 is respectfully requested. If the Examiner believes that a telephone conversation may be useful in advancing prosecution, the Examiner is invited to contact the undersigned at the number listed below. If necessary, applicant requests to extend the period for filing this reply pursuant to 37 CFR 1.136(a) and authorizes the Director to charge any additional fee(s) or any underpayment of fee(s) or credit any overpayment(s) to Procopio Deposit Account No. 50-2075.

Respectfully submitted,
PROCOPIO, CORY, HARGREAVES & SAVITCH LLP

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